Remarks

Claims 39-46 (renumbered 1-8) were pending in the subject application.

In the April 5, 2004 Office Action, the Examiner stated that Claims 42, 43, and 45 (4, 5 and 7) are withdrawn from further consideration as being drawn to non-elected species and that claims 39, 40, 41, 44, and 46 (1-3, 6 and 8) are being acted upon.

By this amendment, applicant has canceled claims 1-7, amended claim 8 and added claims 9 and 10. Accordingly, claims 8, 9 and 10 are pending in the subject application.

In section 5 of the April 5, 2004 Office Action, the Examiner rejected claims 1-3, 6, and 8 under 35 U.S.C. 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In response, without conceding the correctness of the Examiner's rejection, applicant has canceled claims 1-3 and 6 and added new claim 9. Support for new claim 9 may be found, *inter alia*, in Example 12 on pages 18 and 19 of the subject application. Applicant maintains that, new claim 9 is neither vague nor indefinite. Accordingly, applicant requests that the Examiner reconsider and withdraw the rejection under 35 U.S.C. 112, second paragraph.

In section 7 of the April 5, 2004 Office Action, the Examiner rejected claims 1-3, 6, and 8 under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The Examiner alleged that there is insufficient written description to show that applicant was in possession of the "lupus antibodies", other than the anti-R38 antibodies disclosed on page 18, recited in the claims. The Examiner alleged that it is unclear precisely what the term encompasses and that it is likely the term encompasses a genus larger than that disclosed in the specification (anti-R38 antibodies). The Examiner concluded that one of skill in the art would conclude that the specification fails to adequately describe the method of the instant claims.

In response, without conceding the correctness of the Examiner's rejection, applicant has canceled claims 1-3 and 6 and added new claim 9. Applicant maintains that the subject matter of new claim 9 and consequently dependent claims 8 and 10 is described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Accordingly, applicant requests that the Examiner reconsider and withdraw the rejection under 35 U.S.C. 112, first paragraph.

In sections 8 and 10 of the April 5, 2004 Office Action, the Examiner noted that applicant has claimed the benefit of priority to U.S. Serial No. 09/339,494, filed September 20, 1999 (now U.S. Patent No. 6,228,363). The Examiner alleged that the '494 application, however, does not disclose the invention of the instant claims. Specifically, the Examiner alleged that U.S. Serial No. 09/339,494 does not disclose a method of extracorporeal removal of lupus antibodies from a subject's plasma. The Examiner concluded that the benefit of priority to said application is denied and the priority date of the instant application is its filing date, April 4, 2001.

The Examiner then proceeded to reject claims 1-3, 6, and 8 under 35 U.S.C. 103(a) as allegedly unpatentable over Gaubitz, M., et al., Journal of Autoimmunity, (1999), 11:495-501 ("Gaubitz") in view of U.S. Patent No. 6,228,363, issued May 8, 2001 (Naparstek) with a priority date of March 20, 1998 ("the '363 patent") and Madaio, M., et al., Journal of the American Society of Nephrology, (1996), 7:387-396 ("Madaio").

The Examiner acknowledged that the Gaubitz teaching differs from the claimed invention in that it does not teach a method employing a column comprising the R38 peptide nor the use of a Sepharose™ column. However, the Examiner alleged that the '363 patent teaches that the R38 peptide is derived from laminin and is recognized by pathogenic lupus antibodies, referring to column 3, lines 13-19. The Examiner also alleged that Madaio teaches that dsDNA-Ab from lupus patients also recognize laminin, citing particularly the Abstract.

The Examiner alleged it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform a method of treating lupus comprising extracorporeal column immunoadsorption of a subject's plasma for the removal of pathogenic antibodies, as taught by Gaubitz, employing the R38 peptide of the '363 patent. The Examiner further alleged that one of ordinary skill in the art at the time the invention was made would have been motivated to employ the R38 peptide on an immunoadsorption column given the teachings of Madaio that dsDNA-Ab from lupus patients also recognize laminin and the '363 patent that the R38 peptide is derived from laminin and is recognized by pathogenic lupus antibodies.

The Examiner included claim 8 in the rejection and alleged that various types of immunoadsorber matrices (including Sepharose™) for column chromatography were well-known in the art at the time of the invention. The Examiner also alleged that the choice of any particular immunoadsorber matrix would have comprised only routine optimization of the claimed method and would have been well within the purview of one of ordinary skill in the art at the time of the invention.

In response, applicant respectfully traverses the Examiner's rejection on the basis that no motivation for and certainly no expectation of success of applicant's method is provided by the prior art.

The '363 patent only describes the peptides per se; the peptides attached to chromatographic beads were not previously described. The '363 patent does not suggest that any disclosed peptide could be successfully used to treat a subject having systemic lupus erythematosus. It is not clear from the '363 patent whether the peptides could even bind to the pathogenic antibodies once attached to the chromatographic beads. Finally, it would not be obvious to couple the peptides to the column using a coupling buffer.

Gaubitz provides no suggestion or motivation to try other immunoadsorbent agents other than those which it disclosed. Furthermore, Gaubitz provides no expectation that using its method with the peptides of the subject application would be successful. In fact, Gaubitz indicates that the effect of any change to his system cannot be predicted by reciting "However, clear-cut recommendations concerning the choice of type of adsorption column, intensity of treatment and accompanying immunosuppressive treatment cannot yet be given." (see page 500, 2nd column, 2nd full paragraph).

The disclosure of Madaio further confirms the unpredictability of the effects of any attempt at extracorporeal removal of antibodies from the plasma of lupus patients. While Madaio states that anti-DNA antibodies are useful as markers, "serum antibody levels frequently do not correlate with disease activity" (see page 388, 1st full paragraph). Thus, Madaio, as Gaubitz, confirms that the results of the removal of the anti-DNA antibodies from lupus patients are unpredictable.

Therefore, Gaubitz, Madaio and the '363 patent in combination at worst provide a motivation to try, but certainly provide no expectation of success that the recited peptide would function in the claimed extracorporeal method of treating a patient with systemic lupus erythematosus.

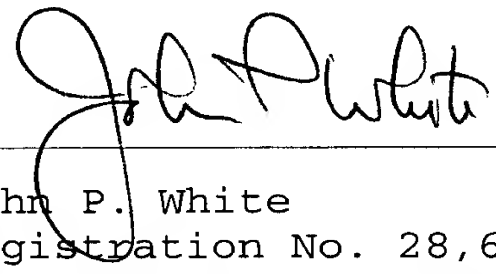
The applicant has achieved unpredictable results by removing 30-60% of the pathogenic antibodies from the plasma of a patient with systemic lupus erythematosus as shown in Table 5 of Example 12 on page 19 of the subject application.

Applicant maintains that new claim 9 and dependent claims 8 and 10 are not obvious over Gaubitz in view of the '363 patent and Madaio. Accordingly, applicant requests that the Examiner reconsider and withdraw the rejection under 35 U.S.C. 103(a).

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee other that the enclosed $980.00 fee for the three-month extension of time is deemed necessary in connection with the filing of this Amendment and a check in that amount is enclosed. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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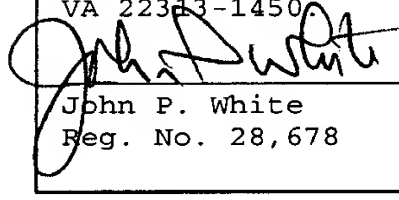
I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



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Date